## REMARKS

Claims 9 and 11 are pending in the application. Claims 10, 12, and 13 have been previously withdrawn from consideration. Claims 1-8 have been previously cancelled. Claim 11 has been amended to correct a typographical error. No new matter is added.

The Examiner has maintained the rejection of claims 9 and 11 under 35 U.S.C. § 103(a) over Weder et al. (EP 733372 or its equivalent US 5726164) ("Weder"). The Examiner states that one of ordinary skill would have readily optimized effective dosages as determined by good medical practice and the clinical condition of the individual patients. Applicants respectfully disagree and request that the rejection be withdrawn.

Applicants have solved the problem of creating a spontaneously dispersible pharmaceutical composition for oral administration of N-benzoyl-staurosporine, which was a need in the art acknowledged by Weder.

Weder teaches that "[A] characteristic but undesirable property of staurosporin and most derivatives thereof is their extremely low water solubility...." (Col 1 ln 39-42). Weder's solution to the problem is to create intravenous dosage forms. (Col 2 ln 4-9).

Weder acknowledges that peroral dosage forms are gaining increasing importance. (Col 1 ln 44-47). However, peroral dosage forms are taught to be disadvantageous compared to intravenous dosage forms because "the metabolism in the gastrointestinal tract to which orally administered therapeutic agents are always subjected, can be substantially avoided" for intravenous dosage forms. (Col 1 ln 53-56).

The Examiner states that Weder acknowledges that there exists general art accepted knowledge in preparing the staurosporin derivative in oral dosage form, citing Col [1] ln 44 through Col 2 ln 9. Applicants respectfully disagree. Instead, Weder specifically states that "[A] suitable intravenous dosage form has not yet been available for the important group of therapeutic agents consisting of staurosporins and staurosporin derivatives ... especially N-benzoyl-staurosporin." (Col 2 ln 4-9)

Numerous publications are mentioned that "propose various means of converting a sparingly soluble therapeutic agent into a more soluble form that is suitable for intravenous formulations." (emphasis added) (Col 2 ln 10-13) Even with such formulations, cases remain where a "lack of solubility remains a problems which is not overcome in spite of the use of the few solubilisers permitted in national pharmacopoeias" (Col 2 ln 15-30). Weder specifically states that staurosporin has a particularly poor water solubility. (Col 2 ln 49-57)

Applicants respectfully submit that there is no suggestion in Weder that routine methods known in the art for optimizing effective intravenous dosage forms would produce all aspects of the instant invention, including especially a spontaneously dispersible pharmaceutical composition for oral administration comprising N-benzoyl-staurosporine. Applicants further assert that Weder teaches away from use of peroral dosage forms for compounds with extremely low water solubility, such as staurosporine and its derivative. As acknowledged by the Examiner on page 3 of the Final Office Action, Weder further differs from the claimed invention in (i) the specific amounts of active and inactive ingredients (claim 9) and (ii) bioavailability levels and dose values of N-benzoylstaurosporine (claim 11). Therefore, one skilled in the art would not be led by the teachings in Weder to design an oral dosage form of N-benzoylstaurosporine, such as that of the Applicants' invention.

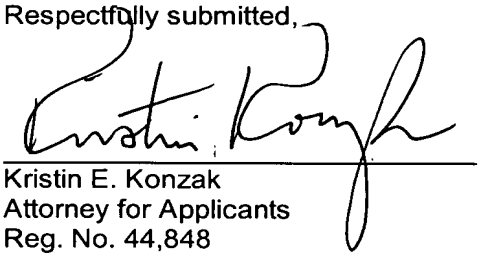
Applicants assert that from a reading of Weder, one skilled in the art would not be motivated to create the Applicants' present invention, and would not be in possession of all aspects of the invention drawn to an oral dosage form of N-benzoylstaurosporine. Therefore, Applicants respectfully request that the Examiner withdraw the rejection based on 35 U.S.C. § 103(a) over Weder et al.

## CONCLUSION

The Applicants believe that the Application is now in condition for allowance and request early notice to that effect.

The Examiner is herein authorized to charge Deposit Account No. 19-0134 in the name of Novartis Corporation for fees which may be properly assessable in the case and to refund fees paid in excess of amounts owed.
If it will advance prosecution of the Application the Examiner is urged to contact the Applicants' undersigned counsel at the telephone number listed below.

Respectfully submitted,



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Date: 13 October 2005